K002258

UltraGuide Ltd.

510(k) Summary

UltraGuide 1000

I. Submitter Information

A. Name: UltraGuide Ltd.

B. Address: Tirat Hacarmel Industrial Park
POB 2070
Tirat Hacarmel 30200
Israel

C. Contact Person: Dr. George Myers, 201-727-1703, Fax 201-727-1708

D. Date of preparation: June 8, 2000

II. Device Data

A. Trade Name: UltraGuide CT – Guide 1010

B. Common Name: System for Interventional Needles for clinical interventions performed under imaging by computed tomography

C. Classification Name: System, X-Ray, Tomography, Computed

III. Legally-marketed predicate devices.

A. Picker Pinpoint, K974513.

B. UltraGuide 1000, K974432

IV. Description

The CT-Guide 1010 provides visual enhancement of the interventional tool by overlaying graphics depicting its relative position and its predicted future path on the CT image of the internal organs, all displayed on the monitor of a personal computer.

V. Intended Use

The CT-Guide 1010 system is a stereotactic accessory for Computed Tomography (CT) systems. It displays the simulated image of a rigid insertion tool, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the CT image of the target organs and the projected future path of the interventional instrument,

compensating for respiratory movements of the patient.

The device is intended to be used in clinical interventions and for anatomical structures where computed tomography is currently used for visualizing such procedures.

VI. Technological characteristics

The device uses a magnetic tracking system comprising transmitters and sensors, sold under the trade name "MiniBird," to determine the location and orientation of the interventional instrument. This magnetic tracking system has been used on medical devices cleared by the FDA. The position and orientations of the interventional devicetool, and the CT images acquired by the CT scanner, are transmitted to a data processor (computer), which makes the necessary calculations to provide the guidance graphic overlay depicting the interventional instrument on the CT image.

VII. Testing

A. Non-clinical tests

The UltraGuide 1000 has undergone extensive bench tests for electrical safety and electromagnetic compatibility. The major components (the computer, and magnetic tracker) are all commercial devices with published environmental and physical specifications.

Accuracy tests were done in phantoms.

B. Clinical Test

Since this system uses the same technology as the predicate device, a clinical test is not necessary. However, scans were taken on representative patients to demonstrate the types of images obtained.

VIII. Conclusion

The tests show that the UltraGuide CT 1010 is equivalent to the predicate devices in safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 8 2000

UltraGuide, Ltd.
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K002258
UltraGuide CT-Guide 1010
Dated: July 24, 2000
Received: July 25, 2000
Regulatory Class: II
21CFR 892.1750/Procode: 90 JAK

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Attachment 1b

510(k) Number (if known): K002258

Device Name: UltraGuide CT-Guide 1010

Indications For Use:

The CT-Guide 1010 system is a stereotactic accessory for Computed Tomography (CT) systems. It displays a rigid interventional instrument, such as a biopsy needle or an aspiration needle, on a computer monitor screen that also shows the CT image of the target organs. The CT-Guide 1010 system also enables compensating for respiratory phases of the patient.

The device is intended to be used in clinical interventions and for anatomical structures where computed tomography is currently used for visualizing such procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Reynolds

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002258

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)